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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/684,883	10/06/2000	Bernard R. Brodeur	047998/0197	3090

7590

07/30/2002

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EXAMINER

NAVARRO, ALBERT MARK

ART UNIT

PAPER NUMBER

1645

DATE MAILED: 07/30/2002

8

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/684,883

Applicant(s)
Brodeur

Examiner
Mark Navarro

Art Unit
1645



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on _____.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 91-173 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claims 91-173 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ | 6) <input type="checkbox"/> Other: |

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Election/Restriction

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 91-94, 104-106, and 116-123, drawn to isolated polynucleotides relating to SEQ ID NO: 1, classified in class 536, subclass 23.7.
 - II. Claims 91, 95-97, 107-109, and 116-123, drawn to isolated polynucleotides relating to SEQ ID NO: 3, classified in class 536, subclass 23.7.
 - III. Claims 91, 98-100, 110-12, and 116-123, drawn to isolated polynucleotides relating to SEQ ID NO: 5, classified in class 536, subclass 23.7.
 - IV. Claims 91, 101-103, 113-115, and 116-123, drawn to isolated polynucleotides relating to SEQ ID NO: 7, classified in class 536, subclass 23.7.
 - V. Claims 124-130, 133-137, and 170-173, drawn to polypeptides, classified in class 530, subclass 350. (Note election of a single sequence is required).
 - VI. Claims 131 and 132, drawn to a method of isolating a polypeptide, classified in class 530, subclass 412.
 - VI. Claims 138-148, drawn to antibodies, classified in class 530, subclass 387.1.
 - VII. Claims 149-154, drawn to pharmaceutical compositions comprising an antibody and methods of treating a patient through the administration of said antibody, classified in class 424, subclass 130.1.

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- VIII. Claims 155-157, drawn to a method of detecting *Neisseria* antigen by incubating an antibody with a biological sample, classified in class 435, subclass 7.1.
- IX. Claims 158-160, drawn to a method for detecting an antibody by incubating an antigen with a biological sample, classified in class 435, subclass 7.92.
- IX. Claims 161-162, drawn to a method of in vivo detection, classified in class 424, subclass 9.1.
- X. Claims 163-169, drawn to methods of detection via hybridization (Note: only one SEQ ID NO. and its fragments will be examined. Applicant must choose one if this Group is elected), classified in class 435, subclass 6.

MPEP 803.04 sets forth that biological molecules with different sequences are separate inventions. Accordingly each sequence recited in the elected polypeptide group has a separate primary, secondary, and tertiary structure, as well as being isolated from separate strains. Consequently, each sequence is considered a separate invention and Applicant is required to select a single sequence for prosecution.

- 2. The inventions are distinct, each from the other because of the following reasons:

Groups I-IV are drawn to different products with different structures. These polynucleotides encode completely different proteins. Accordingly, these polynucleotides are patentably distinct and independent from one another. Groups I-IV, V and VI are drawn to

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biologically, chemically, and structurally different products and are therefore patentably distinct from one another.

Inventions V and VII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the antibodies may be used in a materially different process than in passive immunization procedures, i.e., the antibodies may be used as diagnostics.

Inventions V and VIII or IX are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the antibodies may be used in a materially different process than in a detection method, i.e., the antibodies may be used as therapeutics such as in passive immunization procedures. Additionally, the methods of VIII and IX are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, of different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions, have different modes of operation because one method involves taking a sample from a patient and the other method involves in

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vivo testing. These are very different methods which involve different method steps and reagents.

Inventions V and IX are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the polypeptides may be used in methods other than detection, i.e., they may be used in immunization methods.

Inventions I-V and X are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the polynucleotides may be used for other methods than hybridization, i.e., they may be used to produce recombinant proteins or in recombinant vaccines.

Inventions V and VI are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case, the method of making the proteins can be made in a manner different than recited in claims 131 and 132, i.e., the proteins can be made synthetically .

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Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark Navarro whose telephone number is (703) 306-3225.



Mark Navarro

Primary Examiner

July 29, 2002